IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION
CIVIL ACTION NO. 5:21-CV-00172-KDB-SCR

BELVIN SHERRILL AND AURELIA SHERRILL, **Plaintiffs,** **v.** **SPINALGRAFT TECHNOLOGIES, LLC; AZIYO BIOLOGICS, INC.; MEDTRONIC, PLC; DCI DONOR SERVICES, INC.; MEDTRONIC USA, INC.; NEW MEXICO DONOR SERVICES; MEDTRONIC, INC.; MEDTRONIC SOFAMORE; AND DANEK USA, INC.,** **Defendants.**	**ORDER**

THIS MATTER is before the Court on Defendants Aziyo Biologics, Inc., Medtronic Sofamor Danek USA, Inc. and SpinalGraft Technologies, LLC's Partial Motion to Dismiss (Doc. No. 44),[1] the Memorandum and Recommendation (M&R) of the Honorable Magistrate Judge Susan C. Rodriguez (Doc. No. 56) and Plaintiffs' Objection to the M&R (Doc. No. 57). The Court has carefully considered this motion, the M&R, and the parties' briefs. For the reasons discussed below, the Court will **AFFIRM** the M&R and **GRANT** the Partial Motion to Dismiss.

[1] This Motion was filed by only three of the Defendants: Aziyo Biologics, Inc., Medtronic Sofamore Danek USA, Inc., and SpinalGraft Technologies, LLC. Accordingly, this Order has no effect on the claims brought against the non-moving Defendants and any reference to "Defendants" in this Order refers only to the moving Defendants.

I. LEGAL STANDARD

A district court may designate a magistrate judge to "submit to a judge of the court proposed findings of fact and recommendations for the disposition" of certain pretrial matters, including motions to dismiss. 28 U.S.C. § 636(b)(1). Any party may object to the magistrate judge's proposed findings and recommendations, and the court "shall make a *de novo* determination of those portions of the report or specified proposed findings or recommendations to which objection is made." 28 U.S.C. § 636(b)(1) (italics supplied). Objections to the magistrate's proposed findings and recommendations must be made "with sufficient specificity so as reasonably to alert the district court of the true ground for the objection." *United States v. Midgette*, 478 F.3d 616, 622 (4th Cir.), *cert. denied*, 551 U.S. 1157 (2007). However, the Court does not perform a *de novo* review where a party makes only "general and conclusory objections that do not direct the court to a specific error in the magistrate's proposed findings and recommendations." *Orpiano v. Johnson*, 687 F.2d 44, 47 (4th Cir. 1982). After reviewing the record, the court may accept, reject, or modify, in whole or in part, the findings or recommendations made by the magistrate judge or recommit the matter with instructions. 28 U.S.C. § 636(b)(1).

II. FACTS AND PROCEDURAL HISTORY

This action arises out of post-surgery complications suffered by Plaintiff Aurelia Sherrill following spinal surgery in April 2021. During the surgery, her doctor used FiberCel Fiber Viable Bone Matrix ("FiberCel"). FiberCel "is made from human tissue consisting of cancellous bone particles with preserved living cells, combined with demineralized cortical fiber." Doc. No. 41 at ¶ 21. "[E]ngineered to be like natural tissue," it "is marketed for use in orthopedic and

reconstructive bone grafting procedures with the use of autologous bone or other forms of allograft bone or alone as a bone graft." *Id.* at ⁋⁋ 21-22.

Unbeknownst to Mrs. Sherrill or her medical care team, the FiberCel used was allegedly contaminated with tuberculosis and Mrs. Sherrill began experiencing lower back pain and spasms within a few weeks of the surgery. *Id.* at ⁋⁋ 36-41. By June 2021, the United States Food & Drug Administration and Defendant Azyio Biologics, the developer and manufacturer of FiberCel, issued a voluntary recall in response to reports of patients testing positive for tuberculosis and other post-surgical infections following the surgical implantation of FiberCel as part of orthopedic or spinal procedures. *Id.* at ⁋⁋ 28-29. Mrs. Sherrill was informed that she may have been exposed to tuberculosis from the FiberCel several days later and subsequently tested positive. *Id.* at ⁋ 42.

Ms. Sherrill brought this lawsuit in October 2021 and it was removed to this Court in December 2021. *See* Doc. No. 1. In her Complaint, she alleges that her tuberculosis infection forced her to complete "a grueling medical protocol" which led her to experience further negative side effects. Doc. No. 41 at ⁋⁋ 44, 47. She further alleges that she has suffered "pain and discomfort, severe emotional distress, the loss of daily functions, and economic loss, including, but not limited to, present and future medical expenses, lost earnings, and future lost earning capacity." *Id.* at ⁋ 48. Her husband, Plaintiff Belvin Sherrill brings a claim for loss of consortium. *Id.* at ⁋ 1.

The Defendants filed their Partial Motion to Dismiss in October 2023, asking the Court to dismiss Plaintiffs' breach of warranty claims. In March 2023, the Magistrate Judge entered the M&R, recommending that this Court grant Defendants' Partial Motion to Dismiss because, as described in more detail below, North Carolina law categorizes the procurement, processing,

distribution, or use of human tissue for injection or transplanting as a service, precluding warranty claims.

III. DISCUSSION

The North Carolina Blood and Tissue Shield Statute (the "Statute"), N.C. Gen. Stat. § 130A-412.30, shields "every participating person or institution" involved in "[t]he procurement, processing, distribution or use of whole blood, plasma, blood products, blood derivatives and other human tissues such as corneas, bones or organs for the purpose of injecting, transfusing or transplanting any of them into the human body" from warranty liability. § 130A-412.30. Put more simply, "the procurement of organs is expressly considered for all purposes as the rendition of a service by every participating person or institution." *Slaughter v. Life Connection of Ohio*, 907 F. Supp. 929, 931 (M.D.N.C. 1995).

Plaintiffs object to the finding that the sale of FiberCel constituted a service under the Statute. They argue that the Statute's plain language does not cover a processed-tissue product like FiberCel and is instead intended to cover only the sale of blood, blood products, and human tissue. Thus, the key dispute is whether FiberCel is processed human tissue or, as Plaintiffs contend, a "tissue-based product" which falls outside the scope of the Statute. Doc. No. 57 at 11.

As did the Magistrate Judge, the Court finds that FiberCel is processed human tissue covered by the Statute. The Statute protects from liability any participating person or institution involved in the "processing" of human tissues, including bones, as long as the ultimate purpose is to inject, transfuse, or transplant that tissue into the human body. § 130A-412.30. FiberCel "is made from human tissue consisting of cancellous bone particles with preserved living cells, combined with demineralized cortical fiber." Doc. No. 41 at ¶ 21. "[E]ngineered to be like natural tissue," it "is used as a bone void filler in various orthopedic and spinal procedures." *Id.* As alleged

by Plaintiffs, it "is meant to be used in surgeries and medical procedures." *Id.* at ⁋ 19. Thus, there is no dispute that FiberCel is, at least in part, processed human bone. The question is whether FiberCel has been processed to the point where it is a tissue-based product rather than processed human tissue/bone. As noted by the Magistrate Judge, the word "processing" in the Statute "is not subject to any modifiers implying that only 'simple' processes as opposed to 'complex' ones are covered," and this Court similarly declines to read such a limitation into the Statute. Doc. No. 56 at 6.

In any event, Plaintiffs have not made a plausible showing to support an argument that FiberCel is significantly comprised of synthetic ingredients. They note only that FiberCel is *preserved* in a solution of dimethyl sulfoxide and sodium chloride and allege that other synthetic ingredients, including providone, iodine, Dulbecco's phosphate buffered saline, sodium phosphate, hydrochloric acid, and hydrogen peroxide are used for processing, preservation and storage and only "trace amounts of these solutions may be present" in FiberCel. Doc. No. 57 at 6-7.[2] Therefore, the Court concludes that FiberCel is processed human tissue covered by the Statute.

Were the Court to find that FiberCel is a product, it would still reach the same outcome because the Court finds the reasoning in *Zydek v. Aziyo Biologics, Inc.* to be persuasive.[3] In that case, the court concluded FiberCel was "incidental" to the plaintiff's surgery and "was only potentially useful after its surgical implantation." *Zydek v. Aziyo Biologics, Inc.*, No. 23 C 3016,

[2] Plaintiffs argue that discovery is required to ascertain "the true composition and makeup of FiberCel" before deciding whether it is a tissue-based product or a service under the Statute. Doc. No. 57 at 4. However, their argument is unpersuasive given the detailed understanding of FiberCel they show in their Objection. *Id.* at 6-8.

[3] The Court notes that in their argument Plaintiffs asserted that "[n]o case has yet been tried" with respect to similar claims made involving FiberCel. Failing to inform the Court of cases such as *Zydek* that were resolved (against Plaintiffs' position on this issue) by dispositive motions mischaracterizes those pending matters.

2024 WL 197264, at *2 (N.D. Ill. Jan. 18, 2024) (quoting *Brandt v. Boston Scientific Corp.*, 792 N.E.2d 296, 303 (Ill. 2003)). The court accordingly found that even if FiberCel were a product, "the surgical purpose … transformed what might ordinarily be considered a product into a legal service." *Id.* Thus, even if the Court agreed with Plaintiffs that FiberCel is a product, its conclusion would not change.

In summary, the Court finds that FiberCel, as developed by the Defendants and used in surgeries, is a service under the Statute. Accordingly, Defendants may not be held liable for warranty claims and the Court will affirm the M&R and grant Defendants' Partial Motion to Dismiss.

IV. ORDER

NOW THEREFORE IT IS ORDERED THAT:

1. The M&R entered on March 29, 2024, is **AFFIRMED**;
2. Defendants Aziyo Biologics, Inc., Medtronic Sofamor Danek USA, Inc., and SpinalGraft Technologies, LLC's Partial Motion to Dismiss is **GRANTED**; and
3. This case shall **proceed to trial on the merits on the remaining claims** in the absence of a voluntary resolution of the dispute among the parties.

SO ORDERED ADJUDGED AND DECREED.

Signed: May 3, 2024

Kenneth D. Bell
United States District Judge